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Remarks

Applicants submit the following amendments and remarks in response to the office action and restriction requirement mailed on December 17, 2004, setting a period for response expiring March 17, 2005. Accordingly, this response is timely filed. It is believed that no fee is due. If there is any fee due, the Office is authorized to charge Deposit Account No. 500239. Claims 1-20 are pending in this application. Claims 1-19 are hereby canceled as being non-elected claims as a result of a restriction requirement. Claim 20 has been amended to clarify the scope of the invention. New claims 21-23 have been added. The amendment and the new claims add no new matter. Support for the amendment and the new claims are found in the original claims 17-19, and in the specification as filed on page 1, lines 15-29, and page 6, lines 36-38. Upon entry of this amendment, claims 20-23 are pending in the application.

Election/Restrictions

The Examiner has imposed a two-way restriction in the present application (Groups I-II) as follows:

Group I: Claims 1-19 drawn to a process for preparing a stable hydrate (class 252, subclass 70);

Group II: Claim 20 drawn to a disodium salt of fosfluconazole (class 424, subclass 401).

Applicants' attorney hereby confirmed election of group II for initial examination, without traverse. Applicants reserve the right to pursue the deleted subject matter in a future divisional application.

Rejection under 35 USC §103(a)

Claim 20 stands rejected under 35 U.S.C. § 103(a) as being obvious over the teaching of WO 97/28169. The Examiner states that "The reference does teach the disodium salt of fosfluconazole, therefore there would be a reasonable expectation of success to modify the prior art to arrive at the instantly claimed invention because the prior art teaches disodium salt of fosfluconazole, which one of the ordinary skill in the art would reasonably expect to form the instantly claimed hydrates when put in water."

Applicants respectfully disagree. WO 97/28169 does not teach or suggest that disodium salt of fosfluconazole (hereafter referred to as DSFF) exhibit plurality of hydration forms. The present inventors are the first to find that DSFF exhibits a plurality, i.e., four, of hydrate forms. While sodium salts may form hydrates, it is unusual that such salts have a multiplicity of hydrate states. Quite unexpectedly, DSFF has four different hydrate states, each having its own level of stability. The stability of hydrates is unpredictable. Among these different states, only two of them are found to be stable. Further, the present inventors found that any composition comprising an unstable hydrate form of DSFF, despite possibly containing stable forms, will decompose. Specifically, the inventors in the present case have found that particular hydrates of DSFF having a water content below the trihydrate stoichiometry (about 11% w/w) or above the hexahydrate stoichiometry (about 20% w/w) exhibit thermal and/or chemical instability. Thus, only the trihydrate and the hexahydrate forms of DSFF are stable. Also stable are hydrate mixes having a water content of from about 11% w/w to about 20% w/w. For example, at a water


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content of above about 20% w/w, DSFF exists as a mixture of hexahydrate (stable) and dodecahydrate (unstable). At a water content of below about 11% w/w, the product will exist as a mixture of trihydrate (stable) and monohydrate (unstable). The fact that only those hydrate forms of DSFF (and mixtures thereof) having a water content from about 11% w/w to about 20% w/w are stable, could not have been predicted by one skilled in the art. Amended claim 20 and new claims 21-23 reflect the property of the hydrates required for stability. Thus, contrary to the Examiner's objection, based on the teaching of WO 97/28169, those skilled in the art cannot obtain stable hydrate forms of DSFF as presently claimed.

In view of the above remarks, Applicants respectfully assert that the Examiner's obviousness rejection has been overcome, and request withdrawal of the outstanding rejection. Early allowance of claims 20-23 is requested.

Respectfully submitted,

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Elsa Djuardi, Ph.D.
Attorney for Applicants
Reg. No. 45,963

Pfizer Inc.
Patent Dept.
10777 Science Center Drive
San Diego, CA 92121
Tel: (858) 638-6117
Fax: (858) 678-8233